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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
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66854 7590 08/08/2008 SHAY GLENN LLP 2755 CAMPUS DRIVE			EXAMINER	
			SHEVIN, MARK L	
SUITE 210 SAN MATEO	. CA 94403		ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/588.413 JOHNSON ET AL. Office Action Summary Examiner Art Unit Mark L. Shevin 1793 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 16-27 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 16-27 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 31 July 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)
Notice of Draftsperson's Patent Drawing Review (PTO-948)
Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date 11/06/2006, 12/17/2007, 04/09/2008.

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5 Notice of Informal Patent Application



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DETAILED ACTION

Status

 Claims 16-27, filed as a preliminary amendment on October 25th, 2007, are pending.

Priority

 Applicants' claim to domestic benefit of U.S. provisional patent application 60/569,659, filed May 6th, 2004 has been recorded.

Information Disclosure Statements

3. The information disclosure statements (IDS) submitted November 6th, 2006, December 17th, 2007, and April 9th, 2008 are compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner. Please refer to applicants' copies of the 1449 forms submitted herewith.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Joint Inventors

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. <u>Claims 16-19</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoichi (JP 2000-185999) in view of Recarte (V. Recarte et al. Influence of Al and Ni concentration on the martensitic transformation in Cu-Al-Ni shape-memory alloys. *Metallurgical and Materials Transactions A*, Vol. 33A, August 2002, p. 2581-2591.) and Kravetsky (US 4,915,773 – as a teaching reference).

Yoichi

Yoichi, drawn to a method of fabricating a single crystal of a shape memory alloy (para 0001), teaches that a mixture of Cu, Al, and M (one of Ni, Zn, or Mn) in the range of Al: 10-20 wt%, M: 1-10 wt%, Cu: balance are heated to the melting temperature ± 50 °C (Abstract and para 0009) and pulled to form a single crystal by a method such as the Bridgman method or other means (para 0004).

After holding the single crystals at 1050 °C for 10 hours, they were quenched, followed by polishing to a mirror finish and etching (para 0009).

Yoichi teaches that single crystals of Cu-Al-M systems have superior shape memory alloy characteristics compared to Ti-Ni system alloys and that the use of a single crystal ensures that no intergranular fracture will occur (para 0004).

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Yoichi does not explicitly teach the steps of "pulling a column of the alloy from the melt at a predetermined pulling rate" or "applying a predetermined hydrostatic pressure on the column and heating the column to a predetermined temperature, the predetermined pulling rate, hydrostatic pressure and temperature being sufficient to crystalline the alloy in the column into a single crystal".

Recarte

Recarte, drawn to a study of the effect of Al and Ni concentration on the martensitic transformation in Cu-Al-Ni shape memory alloys, teaches that single crystals of Cu-Al-Ni were grown by the Czochralski-Stepanov method and contain a low dislocation density (p. 2581, col. 2, para 2).

Kravetsky

Kravetsky, drawn to a process for growing crystals from melts, (col. 1, lines 5-10), teaches that the Stepanov method comprises heating the precursor material(s), fusing a seed crystal to the melt to build up a single crystal, and pulling the melt in a column through a capillary system of a shaping unit (col. 2, lines 20-35).

Regarding claim 16, it would have been obvious to one of ordinary skill in crystal growth, at the time the invention was made, taking the disclosure of Yoichi, Recarte, and Kravetsky as a whole, to fabricate a single crystal shape memory alloy by pulling a molten melt of copper aluminum based alloy at a predetermined rate, temperature, hydrostatic pressure and then quenching as Yoichi teaches the basic process of forming a single crystal of Cu-Al-Ni by providing a Cu-Al-Ni melt and states that after using a known crystal growth method, the crystal is quenched. Recarte then teaches that Cu-

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Al-Ni alloys have been successfully grown using the Czochralski-Stepanov method with a low dislocation density and Kravetsky teaches that the Stepanov method involves forming a molten melt and pulling a column of an alloy or material from the melt. Motivation to use the Stepanov method comes from Recarte's teaching the Cu-Al-Ni single crystals are commercially produced using that method. The specific process variable limitations of pulling rate, temperature, hydrostatic pressure being "predetermined" and sufficient to crystallize the alloy to a single crystal are implicitly taught by Yoichi is teaching the one should use a known crystallization method and Recarte's teaching in that Cu-Al-Ni alloys are formed by such a crystal growth method. One of ordinary skill would be recognize that the aforementioned process variables are crucial to the successful formation of a single crystal and with the goal of forming a single crystal in mind, would be motivated to determine them to produce a single crystal.

Regarding claim 17, Yoichi teaches that the alloy was quenched after annealing at about 1050 °C but did not teach the precise temperature from which the alloy was quenched. Recarte teaches that Cu-Al-Ni samples were annealed at 900 °C for 20 minutes and then water quenched at 0 °C (p. 2583, col. 1, para 1), which is "about 850 °C" to the extent that one of ordinary skill would expect single crystals of Cu-Al-based shape memory alloy quenched from those two temperatures to be essentially the same. For all we know the material could have easily lost 50 °C in traveling from the furnace to a quench bucket.

Regarding claim 18. Yoichi teaches a class of Cu-Al-based shape memory alloys that read on the claimed Cu-Al-(Ni, Co, Mn, Fe) alloy. It would have been obvious to

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one of ordinary skill in the art at the time of the invention to choose the instantly claimed ranges through process optimization, since it has been held that there the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See In re Boesch, 205 USPQ 215 (CCPA 1980). MPEP 2144.05, para I states: "In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists."

Regarding claim 19, while none of the cited prior art specifically teaches quenching in salt water, Recarte teaches that the quenching rate is an art-recognized result effective variable effective in controlling the volume fractions of γ_1 '3 martensite with respect to β_1 '3 martensite (p. 2581, col. 2, para 3) and one of ordinary skill in crystal growth would be expected to have an intimate understanding of cooling rate with respect to crystallization, one would be motivated to alter the quenching medium to attain a desired cooling rate to ensure crystallization as the quenching rate is recognized as a result effective variable by Recarte.

5. Claims 20, 21, 23, 24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoichi in view of Recarte and Kravetsky as applied to claims 16-19 above, in further view of Solar (US 6,042,553)

None of the previously cited references teaches forming Cu-Al-based single crystal shape memory alloys into a wire for use as a guidewire in medical procedures.

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Solar

Solar, drawn to the application of linear elastic alloys (shape memory alloys), teaches that guidewires are the most common medical use of shape memory materials (col. 3, lines 8-14) such as Cu-Al-Ni (col. 1, lines 35-55).

A typical guidewire has a core and a polymer sleeve and achieves best performance based on a combination of factors which include a small diameter, smooth finish, straightness, pushability, kink resistance, and torqueability (col. 3, lines 15-19). The diameter of the wire core ultimately determines the diameter of the lumen that can be treated while the finish of a guide wire often affects the performance of therapeutic devices that are slid over the wire since a rough surface will increase the drag on any device (col 3, lines 20-26). Surface friction may be reduced by polishing or through the use of lubricious coatings (col. 3, lines 26-30).

The guidewire should be ground to diameter by centerless grinding (col. 3, line 55 to col. 4. line 32).

Small tubes or hypotubes are also commonly used in the medical device industry. In some applications like drive shafts and guide wires, hypotubes perform a similar function to wires but also have the advantage of a hollow space to perform some other action such as measuring pressure in suit or infusing liquids (col. 4, lines 60-67).

Solar teaches a specific example of his processing method on a guidewire with a diameter of 0.018 inches that is fitted with a lubricious polymer coating (col. 7, lines 18-25).

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Regarding claim 20_it would have been obvious to one of ordinary skill in crystal growth, at the time the invention was made, taking the disclosures of Yoichi, Recarte, Kravetsky and Solar as a whole, to pull the single crystal column such that it forms a length of wire and grinding the surface to the claimed diameter as Yoichi in view of Recarte and Kravetsky taught the process of pulling a crystal melt of Cu-Al-Ni alloy and Solar teaches that shape memory alloys such as Cu-Al-Ni are advantageously employed as medical guidewires and should be ground to an outer diameter befitting the body lumen to be traversed, for example a diameter of 0.018 inches. Motivation to pull the crystal so as to form a length of wire for latter use as a medical guide wire comes from the reasonable expectation of successfully reducing overall processing time and cost by pulling into a wire during the initial crystal growth compared to later wire drawing, cold working, and annealing.

Regarding claim 21. Solar teaches that guidewires should be ground to diameter by centerless grinding (col. 3, line 55 to col. 4, line 32).

Regarding claims 23-24. Solar teaches that finish of a guide wire often affects the performance of therapeutic devices that are slid over the wire since a rough surface will increase the drag on any device (col 3, lines 20-26) and that surface friction may be reduced by polishing or through the use of lubricious coatings (col. 3, lines 26-30).

Regarding claim 26. Solar teaches that small tubes or hypotubes are also commonly used in the medical device industry as guide wires and have the advantage of a hollow space to perform some other action such as measuring pressure in situ or infusing liquids (col. 4, lines 60-67). Kravetsky teaches that single crystals can be

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grown in the shape of tubes with very high precision (col. 1, lines 50-61) and the cross section of grown single crystals can include tubes with round, triangular, and rectangular section (col. 3, lines 50-65). Given that the melt is pulled through a shaping unit, it would have been obvious to one of ordinary skill to form a hollow wire during crystal growth as Solar taught the advantages of a hollow tube in medical applications as a guidewire while Kravetsky teaches that single crystals can be growth in myriad cross sections such as hollow tubes.

Regarding claim 27, as one of ordinary skill had sought to produce a single crystal of Cu-Al-based shape memory alloy for the purpose of high elastic deformation, one would be implicitly motivated to remove any polycrystals in an unstable outer layer by etching or grinding at taught by Solar in forming a smooth wire.

6. <u>Claims 22 and 25</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoichi in view of Recarte, Kravetsky, and Solar (US 6,042,553) as applied to claims 20, 21, 23, 24, 26, and 27 above, in further view of Pai (US 2003/0078465 A1).

The disclosures of Yoichi, Recarte, Kravetsky, and Solar were discussed above, however none of these references specifically teach electropolishing the wire or chemically etching to reduce the diameter and increase flexibility.

Pai

Pai, drawn to minimally invasive medical device, teaches that tensioning wires may be made of shape memory alloys (para 0204). Tapered tensioning wires are ideally suited for vascular conduits since said anatomical conduits tends to decrease in diameter from the proximal ostia to distal locations (para 0208). The addition of holes,

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slots, notches, and other cut away areas allow the stiffness/flexibility to be tailored by multiple techniques including chemical etching (para 0207).

Once the desired structure is formed, the wire should be smoothed to remove any edges by electropolishing (para 0213).

Regarding claim 22_it would have been obvious to one of ordinary skill in crystal growth, at the time invention was made, taking the disclosures of Yoichi, Recarte, Kravetsky, Solar, and Pai as a whole, to further process the formed single crystal wire by electropolishing as Solar taught that the finish of a guide wire often affects the performance of therapeutic devices that are slid over the wire since a rough surface will increase the drag on any device (col 3, lines 20-26) and that surface friction may be reduced by polishing or through the use of lubricious coatings (col. 3, lines 26-30) and Pai specifically taught that electropolishing is a suitable treating for smoothing such structures to be inserted into vascular conduits.

Regarding claim 25. Pai taught that altering the cross section of the wire, such as by adding notches, slot, or otherwise changing the geometry can be advantageously used to alter the stiffness/flexibility of a wire and that such alterations can be accomplished by chemical etching. Given the teaching of using chemical etching, one of ordinary skill would then be motivated to look to acids or acid mixtures that are known to etch Cu-Al based alloys.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 16, 17, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20 and 21 of copending Application No. 11/948,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 20 of '852 discloses a method of making a hyperelastic single-crystal of AlCuNi shape-memory alloy by drawing a single crystal from a melt at a controlled rate and then rapidly quenching the drawn crystal to produce a single crystal. '852 does not specifically disclose "applying a predetermined hydrostatic pressure on the column" but does disclose melting and mixing layers of Al, Cu, and Ni, which would inherently form a Cu-Al based alloy. The predetermined hydrostatic pressure is suggested by the controlled seed pulling rate.

Regarding claim 16, it thus would have been obvious to one of ordinary skill, taking the claims of '852 as a whole, to form a single-crystal shape memory alloy of Cu-

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Al-based alloy as '852 teaches substantially the same process of controlled singlecrystal growth.

Regarding claims 17 and 19, claim 20 of '852 discloses melting layers of Al, Cu, and Ni and mixing them together to form a mixed melt, which suggests that the melt was at least about 1000 °C as the melting point of Ni is about 1455 °C. Claim 21 of '852 discloses quenching the drawn crystal in salt water from 850 °C.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Czochralski – US 1,560,335

Johnson - US 2006/0118210 A1

Johnson - US 2008/0075557 A1

J.C. Brice and P. Rudolph, Crystal Growth, in *Ullmann's Encyclopedia of Industrial Chemistry*, 2007, Wiley-VCH Verlag GmBH, p. 1, 29-42, 50.

Elastamet™ website screen capture, Accessed July 23rd, 2008.

Elastamet[™] brochure from New Discovery Metals, 2007, 1 page.

- L.H. Yahia et al. Bioperformance of shape memory alloy single crystals. *Biomedical Materials and Engineering*, Vol. 16, (2006), p. 101-118.
- **N.B. Morgan.** Medical shape memory alloy applications the market and its products. *Materials Science and Engineering A* 378 (2004), p. 16-23.
- Y. Sutuo et al. Development of medical guide wire of Cu-Al-Mn-base superelastic alloy with functionally graded characteristics. Mater Res Part B: Appl Biomater. Vol. 69B, (2004), p. 64-69.

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- Z.G. Wang et al. Temperature memory effect in CuAlNi single crystalline and CuZnAl polycrystalline shape memory alloys, *Thermochimica Acta*, Vol. 448, (2006), p. 69-72.
- H.-S. Zhang and K. Komvopoulos, Nanoscale pseudoelasticity of single-crystal Cu-Al-Ni shape-memory alloy induced by cyclic nanoindentation. *J Mater Sci*, Vol. 41, (2006), p. 5021-5024.
- C. Qingfu et al. Stabilisation of martensite during training of Cu-Al-Ni single crystals, *Journal de Physique IV*, Collloque C2, Supplement to the Journal de Physique III, Vol. 5, February 1995, p. 181-186.
- P. Sittner et al. Stress induced martensitic transformations in tension/torsion of CuAlNi single crystal tube. Scripta Materialia, Vol. 48, (2003), p. 1153-1159.
- **X.Y. Zhang et al.** The variant selection criteria in single-crystal CuAlNi shape memory alloys. *Smart Mater. Struct.*, Vol. 9, (2000), p. 571-581.
- A.D. Johnson et al. Applications of shape memory alloys: advantages, disadvantages, and limitations. *Micromachining and Microfabrication Process Technology VII*, J.M. Karam and J. Yasaitis eds, *Procedings of SPIE*, Vol. 4557, (2001), p. 341-351.
- S. Fu and H. Xu. The growth characteristics with a shape memory effect, J. Phys.: Condens. Matter, vol. 4 (1992), p. 8303-8310).
- A.V. Zhdanov and L.P. Nikolaeva. Thermal stresses in tubes, produced from a melt by the Stepanov method, during their cooling, *Journal of Engineering Physics and Thermophysics*, Vol. 68, No. 1, (1995), p. 80-89.
- P.I. Antonov and V.N. Kurlov. New advances and developments in the Stepnakov method for the growth of shaped crystals. Crystallography Reports, Vol. 47, Suppl. 1, (2002), p. S43-S52.

-- Claims 16-27 (All pending) are rejected

-- No claims are allowed

The rejections above rely on the references for all the teachings expressed in the text of the references and/or one of ordinary skill in the metallurgical art would have reasonably understood or implied from the texts of the references. To emphasize certain aspects of the prior art, only specific portions of the texts have been pointed out. Each reference as a whole should be reviewed in responding to the rejection, since other sections of the same reference and/or various combinations of the cited references may be relied on in future rejections in view of amendments.

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All recited limitations in the instant claims have been met by the rejections as set forth above. Applicant is reminded that when amendment and/or revision is required, applicant should therefore specifically point out the support for any amendments made to the disclosure. See 37 C.F.R. § 1.121; 37 C.F.R. Part §41.37 (c)(1)(v); MPEP §714.02; and MPEP §241.01(B).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shevin whose telephone number is (571) 270-3588 and fax number is (571) 270-4588. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy V. King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Shevin/

/Roy King/

Supervisory Patent Examiner, Art Unit 1793

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